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Concl

127. A method of implanting the implant of claim 104 comprising implanting the implant of claim 104 at a desired site of a subject.

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IN THE DRAWINGS

Please add Figures 1 and 2 (attached).

IN THE SPECIFICATION

✓ Page 1, after the title, insert --BACKGROUND AND SUMMARY OF THE INVENTION--

Page 4, between text lines 11 and 12 (i.e., after the first full paragraph), insert

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--BRIEF DESCRIPTION OF THE FIGURES

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Fig. 1 shows a single spaghetti-like strand of an implant of the invention (10)

Fig. 2 shows a plurality of spaghetti-like strands (10, 10a) forming an implant, the strands being slidable against one another as shown by the arrows and described herein.--;

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✓ Page 4, between lines 18 and 19, insert --DETAILED DESCRIPTION--; and

✓ Page 13, before claim 1, insert --It is claimed:--

REMARKS

Reconsideration of this application, as amended, is respectfully requested.

Applicant confirms election of Species III, claims 76-103. New claims 104-127 are presented and should be examined together with claims 76-103.

New Figs. 1 and 2 have been added to show an implant characterized by spaghetti-like strands. The specification has been amended accordingly, Support for the Figures and amendments to the specification can be found, e.g., at Example 1 at page 10. The addition of the Figures and amendments to the specification are believed to overcome the objection to the drawings.

Claims 90, 95, 97, 98, 102 and 103 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Ledergerber, and claims 76, 81, 83, 84, 88, 89 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over that reference. Claims 82 and 96 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Ledergerber in view of Perry. Claims 77-80, 85, 86, 91-94, 99 and 100 ere rejected under 35 U.S.C. § 103(a) as allegedly obvious over Ledergerber in view of Taylor. Claims 87-101 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Ledergerber in view of Chapman. Applicant respectfully traverses each of these rejections.

The Examiner specifically refers to Figures 3 and 8 of Ledergerber in support of his position. Figure 3 shows a hollow tube and Figure 8 shows a covering consisting of silicone filaments fused partially to each other an also to a silicone elastomer shell. Ledergeber does not disclose an implant made of spaghetti-like silicone strands according to the invention, nor does that reference disclose a method of implanting the implants of the invention. The silicone filaments or strands 15 disclosed by Ledergerber at col. 9, lines 28-32 do not themselves form the implant. Rather, they are matted and may be affixed to backing 16 or left entirely unattached to anything other than PTFEe filament or ribbon 14. The filaments themselves never form an implant without being attached to other materials.

Furthermore, although Ledergerber does disclose the use of foam at col. 4, lines 8-18, he does not teach that the foam is a strand. The reference only discusses foam as a "partially compressible" structure, and is shown only in a layered fashion in Fig. 9 attached to a backing (See col. 9, lines 28-35).

The subject matter of the presently elected claims differs from the Ledergerber embodiments in that it relates either to single concentrically round strand or a plurality of such strands, wherein single strands are slidable against each other (See, e.g., claims 76, 90, 104). Ledergerber neither discloses or suggests this feature, and the claims are neither anticipated by nor obvious over Ledergerber. None of the secondary references overcome this deficiency in the primary reference, and were merely cited for disclosing various elements of dependent claims.

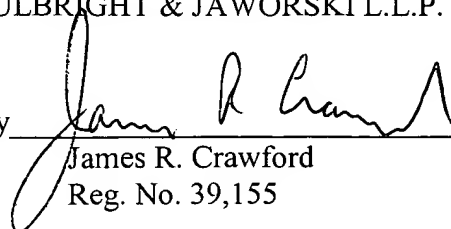
In view of the foregoing, it is submitted that all rejections and objections have been overcome and the application is in condition for allowance. Early issuance of a Notice of Allowance is respectfully requested.

Additional claim fees and any other required fees may be charged to deposit account no. 50-0624.

Respectfully submitted,

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Enclosures



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Medical implants made of structural elements  
TECHNOLOGY CENTER B3700  
**BACKGROUND AND SUMMARY OF THE INVENTION**  
DESCRIPTION

This invention concerns plastic implants for medical purposes and in particular implants composed of thin foldable structural elements.

In human and veterinary medicine congenital or acquired organ or soft-tissue defects are filled using plastic implants (PI) which are operatively introduced into the organism. In contrast to orthopaedic implants or to artificial organs which are also implanted in the organism, the object of the aforementioned plastic implants is to provide volume substitution of soft-tissues and in a particular embodiment to effect stretching and distension of tissue especially of skin tissue.

Typical examples of PI include the substitution of missing mammary tissue by silicone pads which are implanted in front of or behind the pectoral muscle or implants to substitute missing testicles. Examples of implants for stretching and distending tissue to construct soft parts in the face, at the extremities or on the torso are conventional expanders such as e.g. the Becker expander as described by Joseph G. McCarthy, Plastic Surgery (1990), W.B. Saunders Comp., Volume 1, chapter 13, p. 486.

In order to achieve a reconstruction of soft tissues which looks as natural as possible materials are preferably used for plastic implants whose mechanical

volume of lubricant is not as important. In order to construct an implant according to the invention thin foils are for example used as the structural elements wherein numerous layers lying on top of one another yield an implant of the desired thickness.

The desired tissue-like elastic properties of the implant of the present invention are essentially achieved by the ability to displace adjacent layers of the thin foldable structural elements, the sliding effect being mediated and facilitated by a suitable lubricant.

#### BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 SHOWS A SINGLE SPAGHETTI-LIKE STRAND OF AN IMPLANT

The structural elements of the present invention can either be introduced without an outer covering directly into a pre-formed implant pocket in the tissue or, like conventional implants, they can be surrounded by an outer covering in which case the gels of conventional implants are replaced by structural elements of the present invention.

#### DETAILED DESCRIPTION

All physiologically compatible plastics come into consideration as materials for the structural elements. The term "physiologically compatible plastics" in this application generally means naturally occurring and artificially produced materials or biomaterials that are physiologically compatible. In a particular embodiment the structural elements are composed of silicone rubber, silicone rubber made of polydimethylsiloxane being preferred. In a further embodiment structural elements made of polysaccharides are used in which case structural elements made of cuprophane foil represent a preferred embodiment. However, the invention is not limited to the aforementioned materials and other

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of the invention (10)

FIG. 2 shows a plurality of spaghetti-like strands (10, 10A) forming an implant, the strands being slidable against one another as shown by the arrows and described herein.

Claims

IT IS CLAIMED

1. Implant for medical purposes based on a physiologically compatible plastic,  
w h e r e i n  
it is composed of thin foldable structural elements having a surface that is wettable by a fluid lubricant.
2. Implant as claimed in claim 1,  
w h e r e i n  
it is surrounded by a covering.
3. Implant as claimed in claim 1 or 2,  
w h e r e i n  
it has the shape of a foil with a thickness of 10 to 200  $\mu\text{m}$ .
4. Implant as claimed in claim 1 or 2,  
w h e r e i n  
it has a strand form with a thickness of 0.1 to 1 mm per strand.
5. Implant as claimed in claim 1 or 2,  
w h e r e i n  
it is composed of tubular foils.
6. Implant as claimed in one of the claims 1 to 5,  
w h e r e i n  
it has a hydrophilized surface.